

K072183

Section VI: 510(k) Summary

510(k) SUMMARY

Submitter: Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

Date Prepared: July 31, 2007

Contact: Tim Crabtree
Senior Regulatory Affairs Specialist

Device Name: Trade Name: *ST360°*® Spinal Fixation System
Common Name: Rod, hook, and screw spinal instrumentation

Classification: Class III

Product Codes: NKB, MNI, MNH, KWP

Predicate Device: *ST360°*® Spinal Fixation System (K022374, K041925)

Device Description:

The *ST360°*® Spinal Fixation System is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of hooks and/or screws connected to rods and are intended to be removed after solid fusion has occurred. This system includes polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rods in varying lengths, hooks in varying designs, fixed and adjustable transverse connectors. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V), conforming to ASTM F-136.

Intended Use:

The *ST360°* Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

When used as a hook and sacral screw system, the *ST360* Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined as chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic, deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the *ST360*° Spinal Fixation System are intended for the sacral iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

Statement of Technological Comparison:

There are no changes to the material of construction or the mechanism of action to the *ST360*° Spinal Fixation System. The modified system has the same fundamental scientific technology and intended use and indications as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2007

Zimmer Spine, Inc.
% Mr. Tim Crabtree
7375 Bush Lake Road
Minneapolis, MN 55439

Re: K072183
Trade/Device Name: ST360® Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: July 31, 2007
Received: August 06, 2007

Dear Mr. Crabtree:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', written over a horizontal line.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

SECTION V: Indications for Use Statement

INDICATIONS FOR USE STATEMENT

Device Name: *ST360*® Spinal Fixation System

Indications for Use:

The *ST360*° Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion. Pedicle screw fixation is limited to skeletally mature patients.

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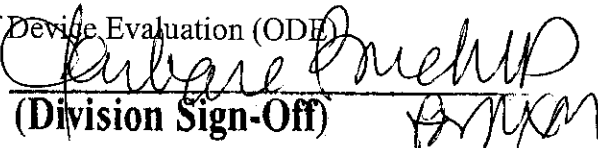
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices